DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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NeuroLogica Corporation
A Subsidiary of Samsung Electronics Co., Ltd
% Ninad Gujar
Regulatory Affairs Manager
14 Electronics Avenue
Danvers, Massachusetts, 01923, USA

December 23, 2014

Re: K142697
Trade/Device Name: NExCT 7
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: September 19, 2014
Received: September 22, 2014

Dear Ninad Gujar,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142697

Device Name
NExCT 7

Indications for Use *(Describe)*

The NLS128 [NExCT 7] system is intended to be used for x-ray computed tomography applications that produce cross sectional images for anatomy that can be imaged in the system aperture. The NExCT 7 is intended to be used for both pediatric and adult imaging and as such has preset dose settings based upon weight and age.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
For
NeuroLogica Corporation
A Subsidiary of Samsung Electronics Co., Ltd
NLS128 [NExCT 7] Computed Tomography System

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR § 807.87(h)

(1) Submitter:

NeuroLogica Corporation
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Danvers, MA 01923

Establishment
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Date this summary was prepared: September 19, 2014

(2) Device Name:

Trade Name	: NExCT 7
Device Model	: NLS128
Classification Name	: Computed Tomography X-ray System
Product code	: JAK
Device classification	: Class II (per 21 CFR § 892.1750)

(3) Predicate device(s):

The legally marketed devices to which substantial equivalencies are being claimed are as follows:

- NeuroLogica Corp., NL4000 BodyTom® Computed Tomography System. This predicate device was cleared under premarket Notification K102677. This is the predicate used for the bulk of comparison of design and labeling.
- Toshiba America Medical Systems, Inc., Aquilion ONE Vision, TSX-301C/1, v4.90. This predicate device was cleared under premarket Notification K122109. This predicate is being used for comparison of detector coverage and rotational speed characteristics.

Both the predicate devices have the same intended use as the new device but different technological characteristics. NeuroLogica NL4000 BodyTom (K102677) is the primary predicate device.

(4) Device Description:

The NExCT 7 system is essentially a higher slice, higher speed, stationary version of our predicate NL4000 BodyTom CT system. It has comparable detector coverage (80 mm), speed (0.25s) and features as the Toshiba Aquilion ONE Vision. It is a high resolution, 128 row, 78 cm aperture, 50cm field of view, Computed Tomography System. The stationary gantry consists of a rotating disk with a solid state x-ray generator, solid state detector array, collimator, control computer, communications link, power slip-ring, data acquisition system, reconstruction computer, power system, brushless DC servo drive system (disk rotation), and patient table with stepper drive translation system. The Power Distribution Unit is a UL listed device. The display/control console consists of a commercial off the shelf (COTS) computer and monitor. The system control software is a modification to the BodyTom software. The system has the necessary safety features such as emergency stop switch, x-ray indicators, interlocks, patient alignment laser, and 110 percent x-ray timer. In addition the system complies with the Medical Imaging Technology Alliance (MITA) Smart Dose standard to optimize and manage radiation dose delivery. This includes radiation protection measures such as the MITA Dose Check Standard and the MITA Access Control Standard.

(5) Intended Use:

The NLS128 [NExCT 7] system is intended to be used for x-ray computed tomography applications that produce cross sectional images for anatomy that can be imaged in the system aperture. The NExCT 7 is intended to be used for both pediatric and adult imaging and as such has preset dose settings based upon weight and age.

(6) Comparison of Technological Characteristics with the predicate device:

NeuroLogica Corporation believes that the NExCT 7 system, for its intended use, is of comparable type in design, material, functionality, technology and is substantially equivalent to the following cleared predicate devices: NeuroLogica BodyTom ref: K102677 and Toshiba America Medical Systems Aquilion ONE Vision, ref: K122109.

Similarities

- **Material:** The NExCT 7 uses similar material to the above listed scanners such as solid state detectors, x-ray generator, slip ring, data acquisition ICs, rotational bearing, and motion control systems.

- **Design:** The NExCT 7 is similar in general design principle to both the above listed CT systems. Specifically, it shares most of the control system designs and features of the NeuroLogica BodyTom and has the rotational speed (0.25s) and detector coverage (80 mm) comparable to the Toshiba Aquilion ONE Vision.

Differences

- **Mobile vs. Stationary**
  The difference between NExCT 7 and the primary predicate BodyTom is that the BodyTom is a mobile scanner and the proposed is a stationary scanner. Mobile scanners require battery power, cannot tilt, and do not have translating patient tables. But these differences are covered by the similarities to the Aquilion scanner which is stationary, with tilt, with translating patient table, and wall power.

- **Detector Coverage**
  The proposed scanner has 80mm of detector coverage, which is more coverage than the BodyTom predicate (40mm), but less than the Aquilion predicate (160mm).

- **Gantry Rotational Speed**
  The maximum rotational speed of the proposed NExCT 7 system (0.25sec) is only marginally faster than the Aquilion predicate (0.275sec). This does not affect the overall safety and effectiveness as the proposed scanner complies and passed all of the referenced IEC mechanical safety tests.

(7) General Safety and Effectiveness Concerns:

All components of the NExCT 7 system that are subject to Federal Diagnostic Equipment Performance Standard and applicable regulations of 21 CFR §1020.30 and §1020.33 are certified to meet those requirements. An initial report as per 21 CFR §1002.10 will be filed with the Center for Device and Radiological Health (CDRH). To minimize electrical, mechanical and radiation hazards, NeuroLogica adheres to recognized and established industry practices.

NExCT 7 system is designed and manufactured to comply with the FDA Quality System Regulations and ISO 13485 requirements. The device is in conformance with the applicable parts of the following FDA Recognized Consensus Standards:

- AAMI/ANSI ES60601-1, (IEC 60601-1), Medical Electrical Equipment - Part 1: General Requirements for Safety; Amd. C1: 2009, Amd. 2: 2010 (3rd Ed.)
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility. Requirements and Test (3rd Ed.)
- IEC 60601-1-3, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment (Ed. 2.1)
- IEC 60601-2-28, Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis (2nd Ed.)
- IEC 60601-2-44, Medical Electrical Equipment- Part 2-44: Particular Requirements for Basic Safety and Essential Performance of X-Ray Equipment for Computed Tomography (3rd Ed.)
- IEC 60825-1, Safety of Laser Products – Part 1: Equipment Classification and Requirements (2nd Ed.)
- NEMA XR 25 (2010) Computed Tomography Dose Check
- ISO 14971:2007, Medical devices - Application of risk management to medical devices
- IEC 61223-2-6, Evaluation and routine testing in medical imaging departments - Part 2-6: Constancy tests - Imaging performance of computed tomography X-ray equipment (2nd Ed.)

In addition, the risk management analysis identified potential hazards which were controlled and mitigated during development of NExCT 7. The verification/ validation testing ensured the safety and effectiveness of NExCT 7. Image quality metrics such as noise, slice thickness, low and high contrast resolution, radiation metrics, and modulation transfer function were measured utilizing phantom image quality tests in accordance with the equipment performance standards for diagnostic x-ray systems administered by the FDA.

8) Conclusion

Based upon the above considerations, NeuroLogica Corporation, subsidiary of Samsung Electronics Corporation, believes that the NExCT 7 Computed Tomography System is of comparable type in design, material, functionality, technology and is, for its intended use, substantially equivalent to the following cleared predicate devices: NeuroLogica BodyTom CT (K102677) and Toshiba Aquilion ONE Vision, TSX-301C/1, v4.90 (K122109).

Use of the NExCT 7 Computed Tomography System does not result in any new potential safety risks. The equipment performs as well in its intended use as devices currently on the market.